Remarks

Applicant also notes that the subject matter of the present application is related to that of co-pending application 10/230/007, which is also before Examiner Myers. The arguments presented by Applicant in response (see the paper mailed September 18, 2006) to the Restriction Requirement in that case are also substantially applicable here.

Applicant again asserts that it has not violated any so-called rule of "improper Markush", rather that the presentation of related species of a generic invention is quintessentially proper Markush practice. Applicant objects to the Examiner's mischaracterization of the plainly proper formatting and content of the claims. Further, the style of subject matter presentation in the claims is classically as permitted -- and as specifically contemplated -- by 37 CFR 1.146 and MPEP803.02 [Restriction-Markush claims], referring to generic claims directed to a plurality of alternatively usable substances or members.

Further, the Office's reasoning (see the Official Action at page 2, lines 5-6) to the effect that a reference against one species would not be a reference against any other species is not being properly applied in the context of a genus/species invention. While Applicant agrees that a reference against one species does not bar patentability of the other species, the discovery of such a reference, in the context of the present case, simply means that Applicant may not be entitled to consideration of a generic claim. However, until such a reference is found, Applicant IS entitled to consideration of a reasonable number of species (MPEP 803.02/ 37CFR 1.146), and Applicant submits that long established rules of administrative practice are being disregarded, for which an explanation should properly be provided. The Examiner has apparently adopted a *per se* rule that only one species will be examined per patent.

Specific Response to Restriction Requirement

Therefore, and nonetheless in full and complete response to the Requirement of Restriction/Election, Applicant elects the species of claim 30, as it depends from Claim 29, and as it is also listed in Claim 29 [as Species No. (1) thereof out of (27) possible species]

According to this Species embodiment, position 601 is "G" and position 1038 is "C", and this species therefore corresponds to Numbered Species XXVI, as the examiner may have intended to number them (note also that the list of species within independent claim 29 is not identical to that within claim 1)

Additional Remarks

Referring to Page 2 of the Official Action, it remains unclear whether the Examiner has been requesting a restriction or an election of species. However, in either case, it is fundamental that the Applicant has the right to define its invention as it sees fit, and it is believed that Claim 29 provides good clarity to the invention, and this is the claim that Applicant wishes, ultimately, to have examined.

To the extent that the species of dependent claim 30 is the only subject matter that the Patent Office is willing, at any time, and in any way, to consider before the present

case issues as a Patent, then Applicant again traverses, as the position articulated in the Official Action is not consistent with established Office practice.

The Applicant also does not agree with the Examiner's re-definition of well established Markush practice before the Patent Office. First, the nucleotide sequences are not "compounds", nor are they required to be, they relate to similar inventions which have similar "properties" and "functions", and are thus eligible for Markush treatment. In fact, Claim 29 is quintessentially written in the very best possible form to qualify for Markush treatment, as must be immediately recognized, and it is not possible to write a more appropriate Markush-style claim.

In Claim 29, Applicant has presented a limited list of specific polymorphic nucleotide "combinations" that are all predictive of schizophrenia, and the recognition of this genus of combinations is the presently claimed invention. Accordingly, there is no explanation in the Restriction Requirement, that is sufficient to overcome the plain meaning and text of 37 CFR 1.146 (as Congress drafted it) and which specifically sets forth that patentably distinct species can be considered together. This is indeed the thrust of MPEP 803.02.

The CFR regulation specifically contemplates (1) that an elected species can be examined first, (2) that a generic claim can be allowed and indeed **it is the responsibility of the Patent Office to determine** if the generic claim can be allowed, and that should the number of species be excessive, examination and allowance might be limited to "not more than a reasonable number". Applicant is concerned that the Patent Office is misreading the applicable Federal regulation so that "not more than a reasonable number" has been reduced *de facto* to "one and only one, and not any more" species. There is no case law that states that 15 species is an unreasonable number. Limiting the Applicant to a single species is not reasonable, nor lawful.

Similarly, in regard of the Examiner's argument that an undue search burden is imposed (a non-statutory ground), it appears that the very search has already, actually, been completed, and the appropriate art identified, and the mere fact that a competitive field exists around this gene (and thus that other researchers have given different names to the gene) is not relevant. Genes can be searched by sequence, not by name, and/or by cross reference to other search parameters.

It should also be noted that the Search needed to evaluate the patentability of each of the species presented in Claim 29 is the very same single search, which all traces directly back to the discovery of the protein named Seq-40 (see WO 01/36473, PCT/US00/31581) which is also owned by Applicants' Assignee, Pharmacia & Upjohn Company, as merged into Pfizer Inc, though an overlapping, but not identical inventive entity made up of employees having an obligation to assign their rights. The present invention is an extension of the earlier work. Accordingly, on indication of allowability of the embodiment of the Claim 30 species, Applicant respectfully maintains its request for rejoinder of a reasonable number of other species.

Applicant also notes that in providing the above assessment of the appropriate scope of the subject matter that should be examined simultaneously, no admission is provided, nor is one required, to the effect that a section 102 or 103 reference against any

species renders unpatentable any other species of the present invention, all of which were believed to be unknown in the prior art. (37 CFR 1.146).

Applicant also notes that "the nucleotides" of the invention are not actual species of polymer (i.e. they are not chemical entities), but rather are specific pieces of information. However, on the Examiner's view that Applicant's nucleotide information equals molecules, and in any case by comparison with the most relevant language in the MPEP, reference should also have been made to MPEP 803.04 [Restriction- Nucleotide Sequences], which clearly states the USPTO's intent to aid the biotechnology industry (see 1192 O.G. 698, November 19,. 1996). Specifically, section 803.04 indicates that up to ten unrelated sequences will normally be considered together, in spite of any rules of restriction. Furthermore nucleotide sequences covering the same protein are always examined together, because, as here, it all relates back to exactly the same prior art being searched. Therefore, whether considered under MPEP 803.02 or 803.04, the Examiner's refusal to consider more than one single species is simply violative of federal law and practice.

Conclusion

The Examiner is welcome to contact the undersigned to discuss the application at any time. Since the application came to be unintentionally abandoned, a Petition for Extension of Time (with fee) is not provided. However, in addition to the accompanying Petition to Revive (fee provided), the Patent Office is nonetheless authorized to charge any fee or fee amount that it determines is necessary so that the present Reply can be acted upon. An early and favorable action is respectfully requested.

Respectfully submitted,

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